DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: MAR 03 2004

From: Lead Reviewer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	*Hoodia gordonii* extract
Firm:	Hoodia products, LLC
Date Received by FDA:	November 4, 2003
90-Day Date:	February 2, 2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya L. Jackson, Ph.D

Tanya L. Jackson, Ph.D Botanist

95S-0316

RPT 218

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, Maryland 20740

JAN 15 2004

Jacob V.O. Mullins, C.E.O.
Hoodia Products, LLC
7429 Rolling Hills Circle
Dublin, CA 94568

Dear Mr. Mullins:

This is to inform you that the notification, dated October 29, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on November 4, 2003. Your notification concerns the substance called "*Hoodia gordonii* extract" that you intend to market as a new dietary ingredient.

The notification informs FDA that Hoodia Products, LLC intends to market the new dietary ingredient, "*Hoodia goordonii* extract", in "mint" form. According to the notification, the dietary product, *Hoodia gordonii* extract in mint, will contain 100 mg of *Hoodia gordonii* extract per piece. The notification states that "one mint should be taken every 3-4 hours; do not to exceed 6 mints in one day".

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully evaluated the information in your submission and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary product, *Hoodia gordonii* extract in mint will reasonably be expected to be safe.

Your notification states that Hoodia Products, LLC, intends to market a "mint" containing 100 mg. of *Hoodia gordonii* extract. The use of the term "mint" is nebulous and is not well defined in your notification. According to Webster's dictionary, a "mint" is defined as "any confection or candy that is flavored with mint (*mentha*) oil." A confection or candy is a conventional food. 21 U.S.C. 321(ff)(2)(B) provides that, among other things, a product that is represented for use as a conventional food is excluded from the statutory definition of a dietary supplement. Therefore, depending on the intended use of your product, it may not be a dietary supplement. The information in your notification does not enable us to determine whether your "Hoodia gordonii extract" mint product is or is not a dietary supplement because you have failed to provide a basis to conclude that it being a "mint" is not in fact a representation that it is being represented for use as a conventional food. In order to determine whether your product is eligible to be a dietary supplement you should provide us information that would enable us to determine whether its use is as a conventional food or dietary supplement. Your notification fails to identify the mint which you intend to market as your proposed dietary product. Inclusion of this information in your notification would have provided clarification about the intended use of your product. Based on your notification FDA cannot determine whether your "*Hoodia gordonii* extract" in mint product is (1) a new dietary ingredient intended to supplement the diet, (2) a new dietary ingredient in a mint delivery system intended to supplement the diet or (3) a substance added to a conventional food.

Your product may also not be a dietary supplement under 21 U.S.C. 321(ff)(2)(A)(i) because it is not intended for ingestion. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is delivered orally, but that exerts its effect prior to being swallowed (for example, a gum, lozenge, or mint that stimulates salivation) or that is a delivery system for a substance that is absorbed buccolingually is not "intended for ingestion." A gum, lozenge or mint preparation which is not intended for ingestion can function as a delivery system for a substance that is absorbed buccolingually. As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

> The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976)

> (defining ingestion as "the taking of material (as food) into the digestive system.")....

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product that is intended to have its effect before it is ingested or that is a delivery system for ingredients absorbed prior to ingestion, is not subject to regulation as a dietary supplement because it is not "intended for ingestion" and may be subject to regulation as a food or drug. You should provide more information that would enable us to determine that your product meets this element of the statutory definition of a dietary supplement. The above matters notwithstanding, if your product is a dietary supplement, there is no information provided in the notification to support your conclusion of a reasonable assurance of safety for your product, "Hoodia gordonii extract" mint.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "*Hoodia gordonii* extract," when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of October 29, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Susan Walker, M.D.
Division Director,
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

FDA NOTIFICATION FOR NEW DIETARY INGREDIENT IN PRODUCT
October 29, 2003

Manufactured by:
Hoodia Products, LLC
(a subsidiary of Mullins & Van de Carr Enterprises, LLC)
7429 Rolling Hills Circle
Dublin, CA 94568

AB/FDA

Name of Botanical:
Hoodia Gordonii (HG) from Asclepiadaceae family

Description of Product:
We are producing a mint that contains 100mg of Hoodia Gordonii extract. The package will contain 12 mints.

100 mg of Hoodia Gordonii extract in each mint

Conditions of Use:
Take one mint every 3-4 hours. Do not exceed 6 mints in one day.

History:
This botanical has been being used by the Southern African tribe called the San people for hundreds of years. It is considered safe by the lack of problems from it. In the past 2 years it has gained some international attention. Pfizer invested $21 million dollars into the R&D of this plant. There are currently a handful of other products on the market that either include HG as an ingredient or as the bulk of the product.

(2 Media sources attached)

Contact:
For any questions please contact:

Jacob V.O. Mullins
jacobvomullins@yahoo.com
PO Box 205679, New Haven, CT 06520
203.623.3990

Sincerely,

Jacob V.O. Mullins
CEO and Founder

86412

◂Return to Ful

LexisNexis™ Academic

ABC News Transcripts

SHOW: WORLD NEWS TONIGHT WITH PETER JENNINGS (06:30 PM ET) - ABC

August 7, 2003 Thursday

LENGTH: 451 words

HEADLINE: DIET FROM THE DESERT **HOODIA** PLANT

BODY:
ELIZABETH VARGAS, ABC NEWS

(Off Camera) Finally tonight, losing weight is a virtual obsession for millions of people in this country and drug companies are constantly trying to develop the latest blockbuster diet pill. Well, now they may have found the secret in the unlikeliest of places. An ancient tribe in southern Africa. Here is ABC's Richard Gizbert.

RICHARD GIZBERT, ABC NEWS

(Voice Over) The Kalahari is 100,000 square miles of African desert. The San people, the bushmen who hunt there, come from a different age. Now, drug companies are tapping into the San's knowledge and betting millions that these bushmen can help the most advanced societies on earth, all because the **hoodia** plant, which the San people have long relied on to survive. "I learned it from my forefather," says this hunter. "It is my food, my water, my medicine." Medicine because a little **hoodia** can kill severe hunger pains and quench the most powerful thirst. For the desert hunter, it is a godsend. Now one man's cure for hunger is turning into another's diet drug. Pfizer, the pharmaceutical giant, has invested $21 million to turn **hoodia** into an appetite suppressant. With 100 million westerners dangerously overweight or obese, the diet drug market is worth $1 billion a year. The San, say the people who study them, were mystified when told the outside world had a weight problem.

NIGEL CRAWHALL, SOUTH AFRICAN SAN INSTITUTE

Why would anybody want to lose weight by taking the **hoodia** plant? Because it's meant for when you're traveling across the desert. So people thought it was a bit weird in the first place

RICHARD GIZBERT

(Voice Over) The drug's developers call the active compound in the plant P57. They say it works by mimicking the effect glucose has on nerve cells in the brain, in effect telling us we're full, even when we are not, thus curbing the appetite. P57 is still a few years from reaching the market, and there has already been a legal battle over it. The first company to patent P57 tried to do it without paying the bushmen any money. One court challenge later, the San had an agreement, they now help cultivate the plant, and should the drug come to market, their impoverished community stands to prosper. "At first we were angry," says this San leader. "Others would get rich and we would stay poor. Now we pray the

product will succeed, and we will benefit." Some of the world's poorest people, who have always had too little, benefiting by helping those who have too much. Richard Gizbert, ABC News, London

ELIZABETH VARGAS

(Off Camera) Anc that is our report on "World News Tonight." I'm Elizabeth Vargas. Have a good evening and good night

LANGUAGE: ENGLISH

LOAD-DATE: August 8, 2003

◂Return to Ful

LexisNexis™ Academic

AAP NEWSFEED

August 24, 2003, Sunday

SECTION: Domestic News

LENGTH: 413 words

HEADLINE: FED: Hunger-killing cactus "could grow in Australia"

BYLINE: By Judy Skatssoon, National Medical Writer

DATELINE: SYDNEY, Aug 24

BODY:
A rare and ugly cactus that grows in the African Kalahari desert is being touted as the latest weapon in the battle of the bulge and potentially the world's first organic weight-loss drug.

Hoodia, traditionally used by the Kalahari's San bushmen to ward off hunger and thirst during long hunting trips, reputedly kills the appetite for 24 hours.

The hunger-quelling ingredient, known as P57, was discovered a few years ago and pharmaceutical giant Pfizer now holds the developing and marketing rights to turn the molecule into weight-loss gold.

It is reportedly being cultivated in industrial quantities at a secret location under armed guard by South African authorities.

But the makers of a BBC documentary to be aired on the ABC's Four Corners tomorrow night believe the conditions are right for the plant - which thrives in hot desert environments - to grow wild in parts of Australia.

"The **Hoodia** thrives only in deserts at a temperature of 50 degrees and over," said Tom Mangold of the BBC's Correspondent program.

"Australia has such an environment. It's just possible the plant grows wild here too."

According to Dr Rich Dixey, the head of UK company Phytopharm which discovered P57, the molecule works by acting on the nerve cells in the brain that sense glucose sugar.

"What **Hoodia** seems to contain is a molecule that's about ten thousand times as active as glucose," he told Mr Mangold.

"It goes to the mid-brain and actually makes those nerve cells fire as if you were full. But you haven't eaten food, nor do you want to."

Animal and clinical trials have backed the findings, with a group of morbidly obese people reducing their calorie intake by about 1,000 calories a day - roughly 50 per cent.

As if that isn't good enough news, **Hoodia** is also said to have euphoric and aphrodisiac effects, according to Mr Mangold, who sampled the plant himself.

On the downside, the plant is said to have an unpleasant taste.

However, the **Hoodia** story has been marred by allegations of bio-piracy and concerns about what the Western discovery will mean to the San tribespeople, who could be turned into millionaires overnight.

Pfizer and lawyers representing the Kalihari Bushmen are waiting for clinical trials to end in about three or four years.

Hoodia has already hit the internet, with a plethora of sites offering information on it and claiming to sell it.

However, experts say it is highly unlikely anything currently available contains **Hoodia.**

LOAD-DATE: August 25, 2003